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Special 510(K) Summary

The following Special 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(c).

APR - 5 2010

Manufacturer Information

Manufacturer:	Paramed Srl
Address:	Corso Perrone 73R 16152 Genova, Italy
Establishment registration number:	3004994584

807.92(a)(1)

Submitter Information

Correspondent:	Joe Ouellette, 39 High Street North Andover, MA 01845 USA. Ph: 978.975.7530 x4345 Fax: 978.975.9930
Contact person:	Joe Ouellette,

807.92(a)(2)

Trade Name:	Mr Inspire
Common Name:	Magnetic resonance diagnostic system
Classification Name(s):	System, Nuclear Magnetic Resonance Imaging
Classification and class of device:	21 CFR 892.1000, class II

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Classification Number: 90LNH807.92(a)(3)

Predicate Devices

Paramed	MrJ	K033507
Paramed	MrJ Extended	K080098

807.92(a)(4)

The Mr Inspire is a magnetic resonance imaging device characterized by an open structure to minimize claustrophobic reactions. The magnet is a permanent "C" shaped joke designed to minimize the installation area and the Controlled Access area in order to fit also very small hospital and clinics.

It is indicated for use as a diagnostic imaging device that produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the following joints: hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ), C-spine, L-Spine with limitation to joint pathologies (no tumors, no angiography).

The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (Tl), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.

807.92(a)(5)

Device Intended Use(s)

The intended use of Paramed's Mr Inspire product is indicated for use as a diagnostic imaging device that produces transverse, sagittal, coronal and oblique cross-sectional images of hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ),C-spine, L-Spine with limitation to joint pathologies (no tumors, no angiography).

807.92(a)(6)

Technological Characteristics

The Mr Inspire MRI system is substantially equivalent to

- Paramed MrJ K033507 under all aspects except some very limited new function due to design restyling
- Paramed MrJ Extended K080098 under all the aspects excluding some design restyling to keep the same drawing lines as the MrJ Inspire

Neither the intended use nor the technological characteristics of this model differ from those of the referenced models.

Paramed s.r.l
Sede Legale e Operativa:
Corso F.M. Perrone, 73r - 16152 Genova
Tel. Fax- ++39 010 7404530
e-mail: info@paramed.it – www.paramed.it

Codice Fiscale e Iscrizione al Registro
delle Imprese di Genova 01195740095
P.IVA 01195740095 – C.C.I.A.A. (REA) Genova 373591
Capitale Sociale € 15 600 I.V.

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The determination of substantial equivalence is based on the design similarities and final inspection report data here referenced and kept in Paramed's files.

A table of the equivalence between the two models is hereunder supplied for the most important specified characteristics:

Parameter	Mr Inspire = MrJ
Magnetic field strength	0.22 T
Stray field 5G	maximum 80 cm from magnet covers
Weight	4200 Kg
Homogeneity	< 5 ppm over 20 cm DSV (FWHM)
SAR (Head worst case)	0,57 +/- 0,15 W/Kg
dB/dt	19,8 T/s with τ = 600 µs Gradient coil diameter 850 mm
FOV	up to 220 mm visualized FOV
Gradient maximum theoretic strength	± 20 mT/m
Gradient maximum clinically employed strength	± 15 mT/m
Slew rate	30 mT/m/ms

807.92(b)(2)

A new Knee coil aimed to host larger anatomies is inserted in this file which is equivalent to the standard cleared knee coil but wider.
Three new linear coils are inserted which can be employed to scan the same anatomies for which the device is cleared but that are flexible and may be opened to be more easily be fitted on the joint to be scanned.
For these coils the clinical output is documented at section Validation activities.

807.92(b)(3)

On the basis of the internal final inspection data reports, summarized in the above 807.92(b)(1) point and of the test images performed both on phantoms and on healthy volunteers, we declare that the Mr Inspire device is at least as safe and effective as the predicate MrJ K033507 cleared device and the same is true for the two Extended kit code 01-1872-00 K080098 and the present one code 01-1872-01. For some aspects it is also safer (due to the fire preventing materials) without loosing its effectiveness, as demonstrated both by the acceptable SNR and by the image quality (phantom and volunteer).

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Paramed S.r.l.
% Mr. Joe Ouellette
Official Correspondent
39 High Street
NORTH ANDOVER MA 01845

APR - 5 2010

Re: K100164
Trade/Device Name: Mr Inspire (code 01-2000-01) with Extended kit (code 01-1872-01)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 8, 2010
Received: March 11, 2010

Dear Mr. Ouellette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K100164

Indications for Use

510(k) Number (if known): K100164

Device Name: Mr Inspire (code 01-2000-01) with Extended kit (code 01-1872-01)___

Indications for Use:

The intended use of Paramed's Mr Inspire with Extended kit product is for diagnostic nuclear magnetic resonance imaging of hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ), with limitation to joint pathologies (no tumors, no angiography) If equipped with the Extended kit (code 01-1872-01) the MrJ Inspire device can also produce images of the C-Spine and L-Spine joints. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joint being imaged.
The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

K100164

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100164